



## TISSUE PACKAGE INSERT

QC-605-F-38 V 4.0

### DESCRIPTION

DONATED HUMAN TISSUE. Tissue grafts are recovered from deceased human donors. All tissue is recovered, processed, stored and distributed for use in accordance with the standards of the American Association of Tissue Banks (AATB). Donor has been determined to be eligible by a Community Tissue Services Medical Director at 349 S. Main St., Dayton, OH 45402 based on the results of screening and testing. Screening includes a review of medical and social history, hospital records, infectious disease screening, autopsy report (if performed), and physical exam. Donors are tested and found negative (acceptable) for anti-HIV 1/2, HBsAg, anti-HBc, anti-HCV, HIV NAT, HBV NAT, HCV NAT and syphilis. U.S. Food and Drug Administration (FDA) licensed test kits are used when available. Additional tests, including but not limited to HTLV I/II, may have been performed and were found to be acceptable for transplantation. Communicable disease testing was performed by a laboratory registered with FDA to perform donor testing and certified to perform such testing on human specimens in accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and 42 CFR part QC-605-F-38 V 4.0

493, or that has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services (CMS).

Paragon 28 allografts are processed aseptically in a controlled clean room environment, following rigorous quality assurance standards. The sterility of the final product is tested using microbiological verification testing per USP <71>, Sterility Tests. Tissue is released for transplantation with final culture results that demonstrate no bacterial growth. Tissue labeled as **STERILE R** has been sterilized to an SAL of  $10^{-6}$  (Sterility Assurance Level). Tissue has been processed with Bacitracin and/or Polymyxin B and traces may remain.

### WARNINGS AND PRECAUTIONS

1. Intended for use in one patient, on a single occasion only.
2. Do not use if package integrity has been compromised. Once the user breaks the container seal, the tissue grafts must be transplanted or discarded.
3. Tissue may not be sterilized or re-sterilized.
4. This tissue is intended for use by qualified healthcare specialists such as physicians, dentists, or podiatrists.
5. Although this tissue has been tested and screened for human pathogens, and processed under aseptic conditions, human derived tissue may still transmit infectious agents.
6. Adverse outcomes potentially attributable to this tissue must be reported promptly to Community Tissue Services.

### TISSUE PREPARATION

#### FREEZE-DRIED TISSUE

1. Inspect for package integrity and expiration date prior to opening.
2. Tissue in peel packages: peel outer package down and aseptically deliver inner package to the sterile field or sterile team member.
3. Remove tissue from inner package and place in sterile basin and cover with normal saline or isotonic solution of choice. Antibiotics of choice may be added.
4. Completely submerge the graft in ambient temperature sterile rehydrating solution. Rehydrate allografts for a minimum of 5 minutes. Rinse the allograft thoroughly with sterile irrigant prior to transplantation. Grafts that are to be manipulated by drilling or cutting may require a longer period of re-

constitution time. Final determination of allograft reconstitution should be made by the physician prior to use.

5. Tissue should be used as soon as possible after reconstitution. If tissue is to be stored for longer than 2 hours after reconstitution, it should be refrigerated at 1 to 10°C in an aseptic container for no longer than 24 hours.
6. **IMPORTANT!** Peel away and remove all internal packaging materials from the graft (i.e. gauze or mesh) prior to implantation.

### FROZEN TISSUE

1. Inspect for package integrity and expiration date prior to opening.
2. **IMPORTANT!** Double packaged graft may be sealed in a non-sterile outer cover. Remove before proceeding.
3. Peel or tear the outer package down and aseptically deliver inner package to the sterile field or sterile team member.
4. Remove tissue from inner package and place in sterile basin and cover with normal saline or isotonic solution of choice. Antibiotics of choice may be added.
5. Tissue should remain in solution until thawed. Tissue thawing temperature should not exceed ambient or room temperature.
6. Tissue should be used as soon as possible after thawing. If tissue is to be stored for longer than 2 hours after thawing, it should be refrigerated at 1 to 10°C in an aseptic container for no longer than 24 hours.
7. **IMPORTANT!** Peel away and remove all internal packaging materials from the graft (i.e. gauze or mesh) prior to implantation.

### STORAGE

**FREEZE-DRIED** tissue must be stored at ambient temperature or colder.

**FROZEN MUSCULOSKELETAL** tissue must be stored at -40°C or colder. Short term storage of up to 6 months is acceptable if tissue is maintained at -20°C to -39°C.

Tissue may not be stored at liquid nitrogen (LN<sub>2</sub>) vapor phase or LN<sub>2</sub> liquid temperatures. It is the responsibility of the Tissue Dispensing Service, Tissue Distribution Intermediary, and/or End User clinician to maintain tissue intended for transplantation in appropriate storage conditions prior to further distribution or transplant.

### TISSUE TRACKING

Recipient records must be maintained for the purpose of tracing tissue post-transplantation. Complete the Allograft Tracking Form on the back of this form and return to Community Tissue Services. Federal Regulations (21 CFR 1271.290(b)) and Joint Commission Standards (TS.03.02.01, EP 7) require proper tracking of this tissue. It is the responsibility of the tissue dispensing service, tissue distribution intermediary, and/or end-user clinician to maintain tissue intended for transplantation in appropriate storage conditions prior to further distribution or transplant.

Community Tissue Services make no claims concerning the biological or biomechanical properties of the provided tissue. Community Tissue Services disclaims all liability and responsibility for any misuse of tissue provided for clinical application.

Community Tissue Services is accredited by the American Association of Tissue Banks. Community Tissue Services – Center for Tissue, Innovation and Research is ISO 13485 certified. Health Canada Registration: 100076.

Please contact Paragon 28 at (855) 786-2828 should you require further information.

### Processed by:

**Community Tissue Services  
Center for Tissue, Innovation and Research  
Manufacturing and Distribution Center**  
2900 College Drive  
Kettering, Ohio 45420  
800-684-7783

### Distributed by:

**Paragon 28, Inc.**  
14445 Grasslands Dr.  
Englewood, CO 80112  
(855) 786-2828





How to return this form	
Email	tissueusage@patienttracking.care
Fax	937-222-2538

## Allograft Tracking Form

FDA Regulations and Joint Commission Standards require tissue tracking systems in all hospitals using allograft tissue for transplantation. In order to comply with these requirements, please complete ALL fields on this form.

Date of Surgery: \_\_\_\_\_

Patient's Medical Record Number or Date of Birth: \_\_\_\_\_

Community Tissue Services does not consider the information requested on this form to be protected health information (PHI), as defined under the HIPAA regulations. Information considered to be PHI by the originator should not be released to Community Tissue Services.

**Place peel-off label for up to 4 allografts or write tissue ID# in the spaces provided.  
One patient, one procedure per tracking form.**

Allograft Tissue ID# _____ <b>Place Peel-Off Label Here</b>
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Allograft Tissue ID# _____ <b>Place Peel-Off Label Here</b>
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Allograft Tissue ID# _____ <b>Place Peel-Off Label Here</b>
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Allograft Tissue ID# _____ <b>Place Peel-Off Label Here</b>
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**If any questions, problems, or adverse reactions occur,  
contact 1-800-684-7783 at 1-937-222-0228.**